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Date: June 20, 2005 Name: Carolyn Beason-Wright Signature: Carolyn Beason-Wright

BRINKS HOFER GILSON & LIONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of:	Matthew M. Graf, et al.
Appln. No.:	09/810,377
Filed:	March 16, 2001
For:	INTRODUCER SHEATH
Attorney Docket No:	8627/092 (PA-5239-RFB)

Examiner: Hook, James F.
Art Unit: 3752

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

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☒ AMENDED BRIEF OF APPELLANT
☒ Return Receipt Postcard

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June 20, 2005
Date

Respectfully submitted,

Lawrence A. Steward (Reg. No. 32,309)

PATENT

Case No. 8627/092 (PA-5239-RFB)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	)
	) Art Unit: 3752
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	) Examiner: Hook, James F.
Serial No.: 09/810,377	)
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AMENDED BRIEF OF APPELLANT

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal is taken from the decision of the Examiner dated October 6, 2004, finally rejecting claims 1, 2, 4-6, 13, 14 and 17-23 of the present application. Appellant timely filed his Notice of Appeal to the final rejection on January 5, 2005.

I. REAL PARTY IN INTEREST

The real party in interest in this matter is the Assignee of the application, Cook Incorporated.

II. RELATED APPEALS AND INTERFERENCES

There are no known prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-23 have been presented for examination.

Claims 1, 2, 4-6, 13, 14 and 17-23 stand finally rejected and are appealed herein.

Claims 3, 7-12, 15 and 16 have been canceled.

IV. STATUS OF AMENDMENTS

No Amendments were filed subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is drawn to an introducer sheath. The introducer sheath comprises a shaft having a proximal end and a distal end. A distal tip section is engaged at the distal end of the shaft. Both the shaft and distal tip section may be formed of fluorinated ethylene propylene, and the distal tip section includes high loadings of a radiopaque material.

An introducer sheath is a medical device that is utilized in the percutaneous insertion of a medical interventional device, such as a catheter or a stent, into a body vessel. An introducer sheath is normally introduced into the body vessel over a dilator. The dilator is then withdrawn, and the interventional device is inserted through the sheath into the patient. Such sheaths are formed of a biocompatible polymeric material, and are frequently provided with a radiopaque ring or band that is spaced about one-quarter inch (0.6 cm) from the distal end of the device. The ring or band imparts substantial rigidity to an otherwise generally flexible segment of the sheath.

Fluorinated ethylene propylene (FEP) is a particularly preferred polymer for use in selected sheaths. FEP has sufficient radial rigidity to enable the sheath to

remain open following removal of an interventional device that has been inserted therethrough. At the same time, FEP has sufficient flexibility to permit it to be manipulated through a body passageway without kinking under conditions of normal use. FEP has a low coefficient of friction, and is a composition with which physicians and clinicians have developed a good deal of comfort and familiarity. Prior to the present invention, it was known to incorporate low-level loadings of radiopaque particles in FEP. However, it was believed that FEP could not be loaded with high amounts of radiopaque particles and still result in a stable, extrudable composition of a type suitable for use in a sheath.

Independent claim 1 is directed to an introducer sheath comprising a shaft (30) extending from a proximal end portion to a distal end portion, and a distal tip section (34) at the distal end portion of the shaft. (Page 4, lines 5-7) The shaft and the distal tip section comprise fluorinated ethylene propylene, and are joined by a thermal bond. (Page 3, lines 6-9; Page 4, lines 13, 14; Page 5, lines 1-4) The distal tip section contains between about 20% and 75% by weight of a radiopaque material selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead. (Page 4, lines 14-21) The shaft is distinctly less radiopaque than the distal tip section. (Page 3, lines 1-4)

Independent claim 14 is directed to an introducer sheath comprising a shaft extending from a proximal end to a distal end, and a distal tip section at the distal end of the shaft. The shaft and the distal tip section comprise FEP. (Page 3, lines 6-9; Page 4, lines 13, 14) The distal tip section contains radiopaque particles, and the shaft is distinctly less radiopaque than the distal tip section. The distal tip section contains between about 50% and 55% by weight of tungsten particles (Page 4, lines 14-16), that range in size from about 1.4 microns to about 1.8 microns. (Page 4, lines 16-18)

Claim 17 is directed to an introducer sheath comprising a shaft having a proximal end portion and a distal end portion, and a distal tip section bonded to the shaft at the shaft distal end portion. The distal tip section consists essentially of fluorinated ethylene propylene containing between about 20% and 75% by weight of

a radiopaque material. The distal tip section is distinctly more radiopaque than the shaft section. (Page 3, lines 1-4)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 2, 4, 13 and 17-23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (U.S. Patent No. 5,221,270) in view of Coneys (U.S. Patent No. 4,657,024).

2. Claim 14 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys and Hopkins (U.S. Patent No. 5,948,489.

3. Claims 5 and 6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4 and 13, and further in view of Hopkins.

VII. ARGUMENT

ISSUE 1.

Claims 1, 2, 4, 13 and 17-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys. According to the Examiner, Parker discloses the recited sheath, but does not disclose the use of fluorinated ethylene propylene (FEP) as the polymeric material. Coneys was cited for its teaching that FEP can be used as sleeves in catheters when used in combination with certain amounts of a radiopaque material. Therefore, according to the Examiner, it would have been obvious to one skilled in the art to modify the polymeric material in Parker to be made of any suitable plastic for use in catheters, including FEP as suggested by Coneys.

Claims 1, 2, 4 and 13.

The present invention is directed to an introducer sheath. In the embodiment of independent claim 1, the sheath comprises a shaft portion formed of FEP, and a distal tip section, also formed of FEP. The shaft and the distal tip section are thermally bonded together. The distal tip section contains between about 20% and

75% by weight of a radiopaque material, and is distinctly more radiopaque than the shaft. Thermally bonding the FEP shaft and distal tip portions together, and providing a high loading of radiopaque particles in the distal tip section of the sheath, provides a very effective introducer sheath having beneficial properties neither taught nor suggested in the cited art.

FEP is a favorable material from which to form the shaft and the distal tip of an introducer sheath. As stated previously, FEP has sufficient radial rigidity to enable the sheath to remain open following passage therethrough of a medical device, and has sufficient flexibility to permit manipulation through a body passageway without kinking under conditions of normal use. FEP has a low coefficient of friction, and is a well-known composition with which physicians and clinicians have developed a high level of comfort and confidence. In addition, FEP is extrudable and has a low coefficient of friction. This property is advantageous when compared to those prior art sheaths formed from copolymers, which have a higher coefficient of friction than FEP. When a material such as FEP having a low coefficient of friction is utilized in a sheath, catheters and other interventional devices can pass through the sheath with much less resistance when compared to a material having a higher coefficient of friction.

In addition to having a low coefficient of friction, it is also desirable that the shaft portion and the distal tip of the sheath are formed from materials that are amenable to the formation of a reliable bond therebetween. Furthermore, it is also desirable that the distal tip section be formed of a material that is amenable to high loadings of a radiopaque material. The present inventors have found that by thermally bonding a shaft portion formed from FEP to a distal tip section formed from highly-loaded FEP that a low friction sheath is formed, which sheath incorporates a reliable bond between the shaft and distal tip, and has a highly radiopaque tip. Such an introducer sheath is neither taught nor suggested in the cited art.

The thermal bonding of a shaft formed of FEP with a highly loaded radiopaque distal tip, also formed of FEP, provides a sheath body having a good

molecular mix of molten materials. The highly loaded tip material does not readily flow into and mix with the shaft material during the bonding process because the tip has a high percentage of filler material. In prior art devices, it is common to have a "cold" bond or an adhesive connection at the interface between the polymeric segments at the bond site. Although such a bond or connection may initially appear to provide a strong attachment between the segments, it may, in fact, be much weaker than desired. The present inventors have addressed this bonding problem by forming both the shaft and the tip from FEP. When discrete polymeric segments of a medical device formed from the same or similar polymers are thermally bonded together, a very secure bond is formed therebetween. On the other hand, when the discrete segments are formed from dissimilar polymers, or when they are joined by a less effective joinder technique, the attachment is generally much less secure. In an introducer sheath, formation of a secure bond between the main shaft body and the distal tip is an important and highly desirable feature. An insecure bond may result in the inadvertent disengagement of the distal tip from the shaft. Such disengagement results in the presence of a free floating embolus (the disengaged tip) in the vascular system. This embolus will eventually lodge somewhere in the vascular system, and presents a risk, among others, of occluding blood flow to tissue.

It is also desirable that the distal tip section be distinctly more radiopaque than the shaft. This enables a physician to accurately determine through fluoroscopy the exact position of the distal tip of the introducer sheath. This can be of utmost importance during a medical procedure when it is desired to insert a stent or other medical device at a precise location of the vasculature. By providing the ability to view the precise location of the distal tip, rather than merely an estimation of the position of the tip that is obtained when a radiopaque ring is used, the physician can accurately determine whether the proper area of the vasculature has been reached for delivery of the medical interventional device. A further advantage to imparting a high radiopacity to the distal tip is that the location of a distal tip may be readily

observed in the vasculature under fluoroscopy in the event that the tip inadvertently becomes dislodged from the shaft during use of the introducer sheath.

In the Office Action, the Examiner emphasized that the Coneys patent was merely cited to teach the use of FEP in a medical tube, and that it was immaterial whether FEP is amenable to high loadings of radiopaque particles, since Parker teaches high loadings of radiopaque particles in a polymeric sheath. Applicants fully understand and appreciate the point that the Examiner makes with regard to the citation of the Coneys reference. Admittedly, the use of FEP in an introducer sheath is known. However, Applicants respectfully state that the present invention involves much more than the mere substitution of one polymer for other known polymers in an introducer sheath. Rather, the present invention teaches the use of the desired FEP polymer in a sheath that may be easily produced by known means (e.g., extrusion), that includes proximal and distal segments securely bonded together, that provides a dimensionally stable sheath, and that includes a highly loaded radiopaque tip.

As stated, claim 1 requires the distal tip section to be amenable to high loadings of radiopaque particles. However, Applicants respectfully submit that it is not sufficient for the Examiner to merely state that a certain polymer is known for general use in an introducer sheath. The invention of claim 1 is directed to much more than this. There must be some teaching or suggestion in the art to believe that the selected polymer (FEP) is capable of being highly loaded with radiopaque particles such that a highly radiopaque distal tip is provided, and that the resulting highly loaded polymer will have sufficient structural integrity for its intended use.

Neither of the cited references teaches or suggests the use of highly-loaded FEP. In fact, Coneys can be fairly read to teach away from the use of FEP as a highly loaded distal tip material. A reference which leads one away from the claimed invention cannot be used to render it unpatentably obvious. See, e.g., *Dow Chemical Co. v. American Cyanamid Co.*, 816 F. 2d 617, 2 USPQ2d 1350 (Fed. Cir. 1987); *In re Grasseli et al.*, 713 F. 2d 731, 218 USPQ 269 (Fed. Cir. 1983). According to Coneys, when highly loaded FEP is used in a medical device, the

highly loaded FEP layer must be surrounded by a covering of virgin FEP. There is no teaching that a discrete FEP radiopaque distal tip section may simply be extruded and bonded onto a proximal section. Rather, the cumbersome steps of enveloping the highly loaded FEP in a layer of pure, virgin FEP were undertaken. As a result, due to the presence of the non-radiopaque envelope surrounding the loaded radiopaque layer, the actual radiopacity of the distal portion of the Coneys tube is limited to a level of between 12 and 25 percent by weight (Col. 3, lines 60-61). On the other hand, in claim 1 of the present invention, highly loaded FEP may be present in the distal tip section at a level between about 20 and 75 weight percent. In claims 2-6, FEP is present in an amount of 50-55 weight percent, which is even further removed from the teachings of Coneys. The distal tip of the claimed structure is capable of providing much better radiopacity than a tip formed according to the teachings of Coneys.

When a primary purpose of the highly loaded FEP layer is to permit precise readings by radiography, the use of the outer layer of virgin FEP runs counter to such purpose (since it is not radiopaque), and detracts from the intended purpose of using a highly loaded layer in the first place. At the very least, it would dilute the strength of a radiographic signal when compared to a signal obtainable with the inventive sheath. Furthermore, there is no reason to believe that the Coneys structure (highly loaded FEP layer embedded in virgin FEP) would provide a sheath wherein the shaft is distinctly less radiopaque than the distal tip section, as recited in independent claims 1 and 14. Accordingly, Applicants respectfully submit that the cited combination neither teaches nor suggests the present invention.

Applicants are mindful that Coneys was cited by the Examiner as a secondary reference, and that the Parker patent was cited as the primary reference to teach features of the invention, other than the use of FEP. However in the final Office Action (page 4, line 11) the Examiner stated that the use of FEP was established in Coneys and that "it was known to [sic] that it could be done..." Applicants respectfully submit that no such teaching results from Coneys, at least in the manner claimed herein. Rather, Coneys teaches that it is necessary to envelope

the FEP in a layer of pure, or virgin, material in order to utilize it in a distal tip. It does not teach or suggest that it could be done without the envelope. The present invention overcomes the existing problem of providing a highly radiopaque FEP distal tip that is securely bonded to a shaft, also formed of FEP. When a prime purpose of utilizing a discrete distal tip bonded to the shaft is to provide a high level of radiopacity to the distal tip, the dilution of such radiopacity in the manner taught in Coneys leads one in the wrong direction. What is desired, and obtainable from the claimed invention, is more radiopacity at the distal tip, not less. Thus, for at least the foregoing reason, Applicants respectfully submit that claims 1, 2, 4 and 13 are not obvious in view of the cited combination.

Claims 17-23.

Independent claim 17, as well as claims 18-23 depending therefrom, differ from claim 1 in that the only recitation of sheath composition in this claim refers to the distal tip portion as "consisting essentially of " high loadings of FEP, and the claim does not recite a specific type of bonding. In the final Office Action, the Examiner stated that even if Coneys was interpreted to require an outer layer of pure FEP in order to maintain structural integrity, as suggested by Applicants, this would not destroy the combination since Applicants have claimed the structure (in claims 1, 2, 4 and 13) using the open-ended term "comprising", rather than the closed-end term "consisting of."

Although Applicants contend that claims 1, 2, 4, and 13 would not be obvious to one of ordinary skill in the art over the cited art for the reasons provided above, claims 17-23 do not utilize the open-ended term "comprising." In independent claim 17, the distal tip section "consist[s] essentially of" FEP containing high loadings of radiopaque material. The use of the phrase "consisting essentially of" in patent claim terminology is well known to restrict the claim scope to recited ingredients and unlisted ingredients that do not affect the basic and novel characteristics of the product defined in the claim. With regard to new claims 17-23, it cannot be fairly said that Coneys teaches or suggests a distal tip of an introducer sheath that consists essentially of highly loaded FEP, since the composite "tip" in

Coneys includes the virgin FEP that envelopes a loaded radiopaque section, and obviously affects the radiopacity of the tip. Furthermore, claims 20 and 21 recite that the distal tip section contains between about 50 and 55 weight percent of the radiopaque material. Thus, for this additional reason, Applicants submit that claim 17, as well as dependent claims 18-23 are also allowable over the cited references of record.

ISSUE 2.

Claim 14 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys and Hopkins. Hopkins was cited for its teaching of the use of tungsten as a radiopaque material, and for teaching that such particles can be as small as 0.9 microns.

As stated above in the discussion of Issue 1, the combination of Parker and Coneys neither teaches nor suggests the use of highly loaded FEP as a distal tip material. Furthermore, the cited combination neither teaches nor suggests a distal tip section containing between about 50% and 55% by weight of tungsten particles. No suggestion is provided in Coneys to provide this level of radiopacity to an FEP sheath, and in fact, Coneys suggests that the weight percent of radiopaque particles will not exceed about 12 to 25 weight percent.

Hopkins was cited for teaching radiopaque materials having particles larger than 0.9 microns. However, Hopkins neither teaches nor suggests the use of an FEP sheath having the features claimed herein. Thus, claim 14 is believed allowable for at least the same reasons that claims 1, 2, 4, 13 and 17-23 are allowable.

ISSUE 3.

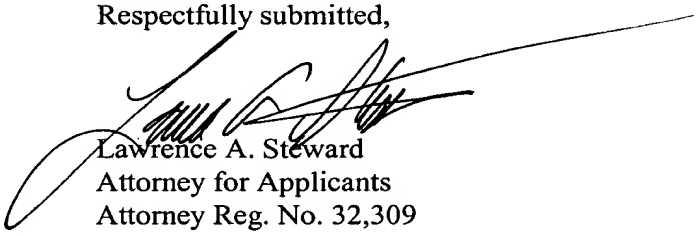
Claims 5 and 6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4 and 13 above, and further in view of Hopkins. Claims 5 and 6 relate to the size of the radiopaque particles in the inventive sheath. These claims depend, indirectly, from claim 1. The claims have been rejected under the same combination of references

used to reject claim 14, and are believed allowable for at least the same reasons that claim 14 is allowable.

CONCLUSION

For the foregoing reasons, Applicants respectfully submit that the grounds for the Examiner's rejections of claims 1, 2, 4-6, 13, 14 and 17-23 are not well taken, and should be reversed by this Board.

Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. An introducer sheath comprising:

a shaft extending from a proximal end portion to a distal end portion; and

a distal tip section at said distal end portion of said shaft;

said shaft and said distal tip section comprising fluorinated ethylene propylene and being joined by a thermal bond, said distal tip section containing between about 20% and 75% by weight of a radiopaque material selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead, and

said shaft being distinctly less radiopaque than said distal tip section.

2. The introducer sheath according to claim 1, wherein said distal tip section contains between about 50% to 55% by weight of radiopaque material.

3. (Cancelled)

4. The introducer sheath according to claim 2, wherein said radiopaque material is tungsten.

5. The introducer sheath according to claim 4, wherein said tungsten particles range in size from about 0.5 microns to about 25 microns.

6. The introducer sheath according to claim 5, wherein said tungsten particles range in size from about 1.4 microns to about 1.8 microns.

7-12. (Cancelled)

13. The introducer sheath according to claim 1, wherein said distal tip section was initially a separate member.

14. An introducer sheath comprising:

a shaft extending from a proximal end to a distal end; and

a distal tip section at said distal end of said shaft,

said shaft and said distal tip section comprising fluorinated ethylene propylene, said distal tip section containing radiopaque particles, said shaft being distinctly less radiopaque than said distal tip section,

said distal tip section contains between about 50% and 55% by weight of tungsten particles that range in size from about 1.4 microns to about 1.8 microns.

15-16. (Cancelled)

17. An introducer sheath comprising:

a shaft having a proximal end portion and a distal end portion; and

a distal tip section bonded to said shaft at said shaft distal end portion, said distal tip section consisting essentially of fluorinated ethylene propylene containing between about 20% and 75% by weight of a radiopaque material, wherein said distal tip section is distinctly more radiopaque than said shaft section.

18. The introducer sheath of claim 17, wherein said shaft comprises fluorinated ethylene propylene.

19. The introducer sheath of claim 18, wherein said distal tip section radiopaque material is selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead.

20. The introducer sheath of claim 19, wherein said distal tip section contains between about 50 and 55% by weight of said radiopaque material.

21. The introducer sheath of claim 20, wherein said radiopaque material comprises tungsten.

22. The introducer sheath of claim 18, wherein said shaft comprises a radiopaque filler.

23. The introducer sheath of claim 17, wherein said distal tip section comprises a fluorinated ethylene propylene extrusion having particles of said radiopaque material dispersed in said extrusion.

IX. EVIDENCE APPENDIX

None.

X. RELATED DECISIONS APPENDIX

None.